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Amendment
Attorney Docket No. S63.2B-10399-US01

Remarks

This Amendment is in response to the Office Action dated June 23, 2004. In the Office Action, claims 9-12, 16-19, 23 and 24 have been withdrawn. Claim 5 has been objected to as being identical to claim 4. All of the remaining claims have been rejected.

New claim 25 has been added. Support for the claim may be found at least in paragraphs 9 and 10 of the published application (US 20030181972). No new matter has been added.

2.

Applicant affirms the election of Species A (claims 1-8, 15, and 20-22, as identified in the Office Action). Claims 13 and 14 are listed in the Office Action as generic.

4.

Claim 5 is objected to because it is said to be an identical copy of claim 4. Claim 5 has been canceled without or prejudice or disclaimer. Withdrawal of the objection is requested.

5.

Claims 1-3 and 8 are rejected under 35 USC 103(a) as being unpatentable over US 5628787 (Mayer) in view of US 5226909 (Evans et al.). The Office Action maintains that because Evans is said to disclose the use of a radiopaque material such as tungsten-rhenium for a housing for a catheter and/or for cutting blades which extend from the housing, it would be obvious to use the material in the stent of Mayer.

Applicant disagrees. Not all metal is suitable for use in expandable implants. For example, some metals may prove too brittle or too soft to be used in expandable devices or, in the case of Mayer, in woven stents where adjacent wires may rub against one another.

Evans does not teach that tungsten-rhenium is suitable for all devices – only that it is suitable for the disclosed housing and/or cutting blades of a catheter.

It is further noted that Mayer discloses a stent in which each of the filaments is a composite including a central core and a case surrounding the core. There is no teaching in either

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of the references, whether taken alone or together, that tungsten-rhenium would prove to be a suitable metal for a composite in the form of a central core and a case. This lack of teaching or suggestion provides an additional round for non-obviousness.

At least for these reasons, withdrawal of the rejection as to claims 1-3 and 8 is requested.

Additionally, as to claim 8, the Office Action states:

The limitation "implant having been made from a sheet of material or from a tube" is not given patentable weight, because this is a product by process limitation. The limitation does not further limit the structure of the device.

MPEP 2113 states that:

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art...where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)

Claim 8, as amended, recites that the implant is formed from a sheet or from a tube, the openings having been formed by removing material from the sheet or tube. This recitation imparts distinctive structural characteristics to the final product. An expandable medical device made from a sheet or a tube expands in a different manner from the woven stent of Mayer. Therefore, the above recitation must be considered in assessing the patentability of the claim.

Neither Mayer nor Evans alone or in combination disclose or suggest an expandable medical device which is formed from a sheet or from a tube, the openings having been formed by removing material from the sheet or tube.

For this reason, claim 8 is further patentable over the proposed combination.

6.

Claims 4, 6, 7, 13-15, and 20-22 are rejected under 35 USC 103(a) as being unpatentable over Mayer in view of Evans, as applied to claim 1 above and further in view of "Tungsten-Rhenium Data Sheet". The Office Action states that "the data sheet lists several

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compositions of tungsten-rhenium alloys that are known to be suitable for medical applications."

MPEP 2128 provides that "If the publication does not include a publication date (or retrieval date), it cannot be relied upon as prior art under 35 U.S.C. 102(a) or (b)". No date is provided for the data sheet. Applicants therefore request that the publication date of the data sheet be provided.

Without conceding that the data sheet constitutes prior art, Applicants further note that claims 4-7 are patentable over the proposed combination for the reasons discussed above in paragraph 5. The cited data sheet, while providing compositions of Tungsten-Rhenium, does not provide any the missing teaching of the suitability of Tungsten-Rhenium for expandable medical device such as those claimed.

Also without conceding that the data sheet constitutes prior art, as to claims 13-15 and 20-22, none of the applied references, whether taken alone or together, disclose or suggest a stent made from a metal which has a modulus of elasticity of 300 GPa or greater. At most, the applied prior art discloses the use of tungsten-rhenium in a particular medical device, namely a housing and/or cutting blades of a catheter, but not in a stent.

Withdrawal of the rejection is requested.

Conclusion

The claims are believed to be patentable over the applied prior art. Notification to that effect is requested.

Respectfully submitted,

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